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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,468	07/10/2000	Morten Sloth Weidner	04590461P	9245

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/13/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/613,468

Applicant(s)

WEIDNER, MORTEN SLOTH

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9,17,18 and 26-38 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 and 19-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-9,17,18 and 26-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt of Request for Continued Examination and Amendment D received on May 23, 2003 is acknowledged. **Claims 1-9, 17-18, 26-38 are pending in this application.** Claims 10-16 and 19-25 have been withdrawn from prosecution as set forth in Paper No. 10.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 4, 27, 29, and 31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 4 recites that the triterpene fraction is in a percent of "at most 100%" which is indefinite. It is unclear whether the amount recited is 100% or no more than 100%. If the claim is reciting 100% of the fraction, is applicant claiming only a triterpene fraction since there is no room for other material?

Claim 22 recites further comprising parkeol, which is indefinite since parkeol's main component is butyrospermol. The claim which claim 22 depends from already recites at least 2% butyrospermol. Further, is the 1% referring to only germanicol or to the entire Markush group. The same issue is present in claim 29 with the recitation of parkeol.

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Claims 31 recites "triterpene fraction together with the sterol fraction is in a weight percentage of at most 100%." The recitation of "at most" is unclear. Is applicant claiming a composition with at least 100% or more than 100%?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Zabotto et al (4,661,343).**

Zabotto et al disclose a cosmetic preparation containing karite oil from the tree *Butyrospermum Parkii*. The karite oil contains 1.2-1.5% unsaponifiable material. This material contains 60-66% sterols and 10-15% triterpenic alcohols of total unsaponifiable material. The triterpenic alcohol contains 16% lupeol, 46% alpha-amyrin, 10% beta-amyrin, and 26% butyrospermol of total alcohol fraction (Note col. 1, line 58 to col. 2, line 62). The composition contains 1-80% karite oil and the reference exemplifies several weight percents. The composition is in the form of an emulsion and is topically administered (Note examples). Zabotto et al disclose that karate oil is known for its protecting and softening effect on the skin. Further, karite oil is known to protect the skin against erythema. (Note col. 1, lines 41-50)

***Response to Amendment***

The Declaration under 37 CFR 1.132 filed August 20, 2002 is insufficient to overcome Zabatto et al upon further consideration. The examiner points out that in applicant's calculation, applicant erroneously divided by 100. The karite oil contains 1.2-1.5% unsaponifiable material. Within this material about 10-15% is triterpenic alcohol and 60-66% is sterols. Therefore, for instance when the alcohol is divided by the total unsaponifiable material, the alcohol fraction is 10% and the sterol is 44% of the total karite oil. Thus the karite oil actually contains 4.6% alpha-amyirin, 1% beta-amyirin, 2.6% butyrospermol, and 1.6% lupeol. The weight percent remains the same regardless of how much of the oil is used, therefore applicant's percentages based on 1-80% is an incorrect comparison. Note applicant is reciting percentages of amyirin, lupeol, etc. within the karite oil and not the total cosmetic/pharmaceutical composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-3, 5, 7-9, 17-18, 26-30, and 32-38 are rejected under 35 U.S.C.**

**103(a) as being unpatentable over Laur et al (5679393).**

Laur et al teach a pharmaceutical composition with shea butter fractions containing triterpene alcohols and sterols (col. 111, lines 40-51). Laur et al teach the composition in a topical emulsion form containing 1-60% unsaponifiable material (Note examples). Laur et al also teach that the mixture may be incorporated in an amount of 0.5-99%. See column 5, lines 45. The unsaponifiable material contains sterols, karitenes, and triterpene alcohol. See column 11-12. The amount of lupeol, amyirin, sterols, and butyrospermol in the triterpene fraction are inherent (also based upon applicant's calculations on page 4 of arguments of paper no. 15). Laur et al disclose the unsaponifiable material from shea butter and other plants, have valuable properties for the fields of cosmetology, pharmacy, or medicine (col. 2, lines 29-33). Lastly, Laur et al teach the composition has anti-inflammatory activity. See column 5, lines 24-25.

Laur et al does not exemplify instant amount of lupeol or butyrospermol of the total composition.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance of Laur et al and manipulate the amount of lupeol or butyrospermol desired in the composition. One would be motivated to do so since Laur teaches approximately 4.4% of butyrospermol and 3.9% of lupeol in one embodiment

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based on 30% unsaponifiable material. However, Laur et al does teach utilization of 99% of the unsaponifiable material. Thus, based on the amount of unsaponifiable material utilized the amount of the individual components will change and the prior art's teachings clearly extend into the instant range of lupeol or butyrospermol in the total composition. Further the desired concentration of each individual component depends on the nature and process of extraction and = Laur et al provides the general guidance of shea butter extraction. The mere optimization of ranges of prior art conditions through routine experimentation does not support patentability of subject matter encompassed by the prior art unless there is evidence of unexpected results.

Lastly, is deemed obvious to one of ordinary skill in the art at the time the invention was made to provide the karite composition in a topical or systemic dosage form since dosage forms are known to a skilled practitioner in the art. The dosage form depends on the area and symptoms to be treated, thus one would be motivated to use the appropriate dosage form according to the condition to be treated.

### ***Response to Arguments***

Applicant argues that Laur et al' compositions contains other native constituents that are found in shea butter. Applicant argues that Laur teaches a preferable amount of 5 or 15% and maximally contains 30% of unsaponifiable amount. Lastly, applicant calculates the weight percent of each individual component. Applicant states that the fraction contains 21% butyrospermol, 51% amyirin, and 18% lupeol and the composition contains 21% triterpenic fraction, 4.4% butyrospermol, 10.6%% amyirin, and 3.9% lupeol.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out the claim language allows for other components in the composition such as "native constituents of shea butter." Secondly the examiner points out that disclosed examples or a preferred embodiment does not constitute a teaching away from the broader disclosure. Therefore, even though Laur et al only exemplifies 1-60% of unsaponifiable material, clearly the reference teaches a broader range of 0.5-99%. Furthermore, the rejection is made under obviousness and the art need only suggest an embodiment rather than exemplify it. However, for arguendo sake the examiner will use applicant's calculated amounts based on Laur's preferred embodiments to address the rest of the arguments. As demonstrated by applicant, Laur et al clearly teaches at least 5% of a triterpene fraction in a cosmetic composition. Applicant recites 5-90% of lupeol or butyrospermol in the total composition and argues that Laur et al only teaches 4.4%. Accordingly 4.4% is an obvious range to 5% and as set forth above, optimization of concentrations is an obvious skill in the art. Lastly, it is quite clear from the art that shea butter or karite oil inherently contain the individual components recited by applicant as seen by the examiner's art cited and applicant's arguments on page 4 that "using data from publicly available sources...the relative content of triterpenes in the unsaponifiable material of shea butter ranges from 65-75% and karitenes in the amount of 18-30%." In regards to arguments that it is not within the skill to calculate the amount of inherent components since one has to combine Laur et al and public literature, the examiner points out the skill of calculating an *inherent* weight percent of a component does not extend patentability.



**Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laur et al (5679393) in view of SU 1181171.**

As set forth, Laur et al a composition with shea butter fractions containing triterpene alcohols and sterols, which has anti-inflammatory activity (col. 111, lines 40-51).

Laur et al do not teach Calendula officinalis in the composition.

SU 1181171 teaches the anti-inflammatory properties of the marigold plant and its extract (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add marigold extract in Laur et al's composition. One would be motivated to do so with a reasonable expectation of at least an additive if not a synergistic effect in the composition since Laur teaches the anti-inflammatory activity of the composition and SU 1181171 teaches the anti-inflammatory properties of marigold.

### ***Response to Arguments***

Applicant arguments do not specifically pertain to instant rejection and only argue Laur et al. Applicants arguments have been addressed above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone numbers

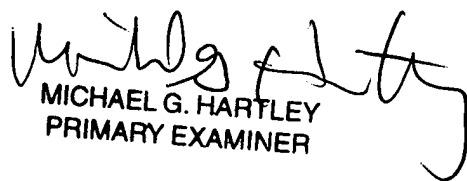
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for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

August 5, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER